Guidance for Industry

Questions and Answers Regarding Establishment and Maintenance of Records

Guidance

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
September, 2005

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Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

On December 9, 2004, FDA issued a final rule that requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. The final rule implements Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (See 69 FR 71562; December 9, 2004 (http://www.cfsan.fda.gov/~dms/frrecord.html)).

This document is being issued as Level 1 guidance pursuant to 21 CFR 10.115 and includes answers to inquiries regarding the implementation of the Establishment and Maintenance of Records Final Rule (21 CFR Part 1, Subpart J). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate. New editions of this guidance may be issued at a later date that include additional inquiries on the implementation of this regulation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. QUESTIONS AND ANSWERS

A. Who is Subject to this Rule? (Section 1.326)

1. General Questions

1.1 Q: A brokerage division of a shipping company handles nationwide shipping needs for several other shippers. The brokerage division does not physically take custody of the food, but negotiates the freight rates and assigns the contracts to independent carriers. Does the brokerage division have record keeping obligations under this regulation?

A: Yes. 21 CFR 1.328 defines a transporter as a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting it. For the purpose of this regulation, a person, such as the shipping company above, who enters into a contract to transport an article of food and has control over the food is considered a transporter, even if the actual transport is subsequently subcontracted to another entity. In the above example, the freight broker and the independent carrier are transporters subject to the Final Rule in accordance with 21 CFR 1.352. This scenario differs from that described in the response to comment 16 in the Final Rule preamble, in which FDA states that the recordkeeping requirements do not apply to brokers who act *only* to facilitate distribution, sale, or transportation of food by processing information or paperwork associated with these functions, such as customs brokers who file entry information on food imported or offered for import with U.S. Customs and Border Protection. Brokers who do not *directly* manufacture, process, pack, transport, distribute, receive, hold, or import food are not subject to the requirements of this regulation.

1.2 Q: A firm purchases bottled water for use by its employees. Does this firm have to establish and maintain records?

A: Yes. The firm must establish and maintain records of the nontransporter and transporter immediate previous sources of the bottled water in accordance with 21 CFR 1.337. However, 21 CFR 1.327(d) excludes persons who distribute food directly to consumers from the requirements in 21 CFR 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. Therefore, the firm does not have to establish records of distribution to its employees.

1.3 Q: Drug manufacturers often compound their products using various excipients (e.g., lactose, sugar alcohols, amino acids, and beta-carotene) that are obtained as food-grade material. Are the drug manufacturers who obtain these materials covered by this regulation? If another company provides one of these materials to the drug manufacturer, is that transaction covered by this regulation?

A: No. 21 CFR 1.326(a) requires that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food (including food ingredients) must establish and maintain records as required by this regulation. However, if a food ingredient is transferred to an immediate subsequent recipient who will use that substance as a drug excipient, FDA considers the substance to be a drug component regulated under applicable drug statutory and regulatory provisions. FDA is not requiring the original firm, the transporter, and the recipient (the drug manufacturer) to establish and maintain records of this transaction. Conversely, if a firm manufactured a substance intended primarily for use as a drug excipient, but sold some of that substance for use in food or feed, the firm would have to establish and maintain records of that transaction.

1.4 Q: Are over the counter vitamins covered by this regulation?

A: Yes. Food in this regulation has the same meaning as under section 201(f) (21 U.S.C. 321(f)) of the Federal Food, Drug, and Cosmetic Act. Food includes dietary supplements, such as over-the-counter vitamins (21 U.S.C. 321(ff)).

1.5 Q: Halloween candy is donated to a firm's distribution center and then distributed to the firm's retail stores to be given out to children. There is currently no record kept of the candy receipt or distribution to retail stores. Is the practice exempt from this regulation?

A: 21 CFR 1.326(a) requires that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food must establish and maintain records as required by this regulation. However, as discussed in the response to comment 13 of the Final Rule preamble, a vertically integrated company does not have to establish and maintain records of internal transactions. The distribution center must always establish and maintain records of the transporter and nontransporter immediate previous sources of the candy, but if the distribution center, transporter, and retail store are all part of the same company under identical ownership, distribution to retail stores is considered an internal transfer for the purpose of this regulation and no records of the transaction must be established and maintained. If the distribution center is not integrated with the retail store (e.g., not part of the same company), or if an independent transporter carries the candy between them, then records of this transaction must be established and maintained. Finally, 21 CFR 1.327(d) excludes persons who distribute food directly to consumers from the requirements in 21 CFR 1.345 to establish and maintain records to identify the nontransporter and transporter subsequent recipients as to those transactions. Therefore, the retail store does not need to establish records identifying the immediate subsequent recipients of the candy if those recipients are consumers.

1.6 Q: A facility manufactures fruit and vegetable salads, and the waste is removed by an outside entity that may direct it to a landfill, compost, or animal feed. Is the facility required to track the waste?

A: FDA intends to consider exercising enforcement discretion if a facility manufacturing fruit and vegetable salads releases food waste to a nontransporter immediate subsequent recipient who directs the waste to a landfill or compost facility or to a facility for consumption by animals without further manufacturing/processing. FDA does not intend to consider exercising enforcement discretion with regard to 21 CFR 1.345, however, if the waste will be further manufactured/processed (e.g., by rendering facilities) before it is consumed by animals, or if there is more than one intermediary (transporter or nontransporter) between the manufacturing facility and the facility where the waste is a disposed of at a landfill or compost facility or is consumed by animals.

2. Intrastate (Reserved)

B. Who is Excluded From All or Part of the Regulations? (Section 1.327)

3. General Questions

FDA has addressed questions we received on this issue in the Final Rule.

4. Farms (Reserved)

5. Restaurants

5.1 Q: Some retail stores have sushi makers on site. The sushi maker prepares sushi in a store and sells it through that store. The retailer never actually owns the sushi, but only retains a portion of the net amount received from the sushi sales. In this case, is the retailer required to keep any records regarding the sushi?

A: No. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to this regulation, in accordance with 21 CFR 1.326(a). Section 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. In the above example, both the owner of the food (the sushi maker) and the retailer who controls the surrounding facility are nontransporters subject to this regulation with respect to the sushi, unless an exemption applies. In this case, the sushi is prepared and sold directly to consumers for immediate consumption, in accordance with the definition of "restaurant" in 21 CFR 1.328. As discussed in the response to comment 37 of the Final Rule preamble, all sales of food prepared and sold directly to consumers for immediate consumption fall under the restaurant exemption, regardless of whether the seller is a retailer or another type of entity. Therefore, in accordance with 21 CFR 1.327(b) the retailer and sushi maker are excluded from all the requirements of this regulation with respect to the food (sushi) prepared and sold directly to consumers.

6. Retail Facilities

6.1 Q: Is a retail store with an in-store bakery also a manufacturing facility that must track ingredients and lot numbers for its baked goods manufactured on-site?

A: No. 21 CFR 1.328 defines a restaurant as a facility that prepares and sells food directly to consumers for immediate consumption. The bakery in a retail store that prepares and sells food in the retail store is considered a restaurant for the purpose of this regulation. Section 1.327 excludes a restaurant from all requirements of this regulation, including the requirement to establish and maintain records of all food it receives (21 CFR 1.337). Therefore, the retail store does not need to track ingredients and lot numbers for the baked goods manufactured on-site.

6.2 Q: A retailer buys bulk packs of food (e.g., fish) and prepares it for resale in smaller quantities. Is the retailer considered a packager? If the food is placed in a new container, must the retailer track the packaging?

A: 21 CFR 1.327(e) states that a retail food establishment may pack food and retain its retail designation if the annual value of food sold directly to consumers is equal to more than half of its total sales. If this condition is met, the establishment still must establish and maintain records of the receipt of the finished container (packaging) that contacts the fish in accordance with 21 CFR 1.327(k), but is excluded from the requirement in 21 CFR 1.337(a)(4) to record the lot or code number or other identifier of the packaging. Section 1.327(d) excludes a retail establishment from the requirement to establish and maintain records for the food it releases, including the source of the

finished container in which the establishment has placed the food, for those products it distributes directly to consumers.

6.3 Q: Some retail stores have sushi makers on site. The sushi maker might prepare sushi in one store and sell it through both that store and other stores. The sushi maker handles all transportation, and the retailer does not own the sushi, but only retains a portion of the net sales. Would the sushi maker be considered a central kitchen (i.e., not a restaurant) with respect to the sushi that is sold in other stores?

A: No. The sushi remains in the continuous possession of the sushi maker (including transport between stores) until it is sold to consumers for immediate consumption. Therefore, the sushi maker functions as an integrated company that prepares and sells food directly to consumers and is considered a restaurant for the purpose of this regulation.

6.4 Q: In a central kitchen in one of its stores, a retailer makes a prepared salad or bakery item that it distributes for sale at multiple stores in the region. Is lot number tracking for ingredients and finished products required?

A: No, provided all of the multiple stores are under the same ownership as the central kitchen. In this situation, the retailer prepares the salad or bakery item and retains that food within its person until it is sold directly to consumers. This retailer is exempt as a restaurant from the requirements of this regulation in accordance with 21 CFR 1.327, for the food it prepares and sells directly to consumers for immediate consumption. If, however, the retailer's central kitchen is preparing and distributing the food to other retailers with different ownership, the retailer's activities would not qualify for the restaurant exemption as to those transactions and would be subject to this regulation for that food.

6.5 Q: Some retail stores donate old produce to pig farms for free. The donated produce is eaten by the animals and reduces the waste produced by the retail store. However, the farms are not considered non-profit organizations. Does this mean that each store that donates in this way will have to document the donations?

A: Similar to Question 1.6 above, FDA intends to consider exercising enforcement discretion regarding records of food waste released by a facility to a pig farm for consumption by animals without further manufacturing/processing.

6.6 Q: A retail establishment releases food to a business. Damaged goods may be sold to third-party reclamation centers or salvagers for eventual resale to consumers. The retail establishment is aware that the nontransporter immediate subsequent recipient in these transactions is not a consumer. However, there is not currently a system in place that can provide information on the specific foods released. Instead, generic descriptions are used (e.g., one pallet of dented cans). 21 CFR 1.327(e) states that for retailers, the requirements in 21 CFR 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available. The response to comment 38 in the Final Rule preamble states that "information is reasonably available to you if you have a system in place to capture the information. FDA does not intend to require the reconfiguration of business operations." In the

situation described above, is the retail establishment required to establish and maintain records of the nontransporter and transporter immediate subsequent recipients?

A: Yes. 21 CFR 1.327(e) provides: "Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in 21 CFR 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies to those transactions only to the extent that the information is reasonably available." FDA considers the information that must be "reasonably available" in this subsection to refer to the retailer's *knowledge* as to whether the recipient of the food is a consumer or a business; it does not exempt the retailer from keeping required records when the retailer knows the recipient is a business and is able to capture this information. For example, if a person buying deli meat from a grocery store owns the sandwich shop in the same shopping complex, the grocery store does not have to inquire as to whether the buyer is purchasing the meat in her individual capacity as a consumer, or purchasing the meat for use in her sandwich shop, nor does the store have to establish separate business accounts to capture the status of the buyer. If, however, the grocery store provides membership cards for buyers based on their status (e.g., one type of card for consumers and another type for businesses), then this information is reasonably available to the retail store, and records of the release of food to businesses are required. In the question posed above, the retail store is aware that the recipient is a business, and the salvaged food is sold on the basis of that understanding. The retail store does not qualify for the exclusion for sales to consumers for these transactions, and must establish and maintain records of the released food as required by 21 CFR 1.345, including an adequate description of the food released.

7. Persons Under the Exclusive Jurisdiction of USDA (Reserved)

8. Food Contact Materials

8.1 Q: The final regulation requires the person placing a food directly into contact with its finished container to establish and maintain records on the container that contacts the food. Since the definition of food includes food ingredients, this requirement appears to apply to equally to anyone placing any food ingredient into any container as well as commercial packaging operations. This encompasses activities such as a chemical plant placing bulk oil or glycerin into a railroad tank car, placing grain into a grain silo, loading product into drums, loading a tank truck, or placing vegetables into a pick-up truck, as well as more traditional food packaging operations such as filling a bottle of ketchup or canning tomatoes. Does "finished container" apply to every container at every step in the chain of custody?

A: No. A "finished container" as described in 21 CFR 1.27(k) is the packaging in which the finished food will be received by an individual consumer (not by a business).

8.2 Q: A transporter carries items that may or may not become food contact substances (e.g., polyethylene bags). Is the transporter subject to the records access requirements?

A: In accordance with 21 CFR 1.327(j), all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all recordkeeping requirements except 21 CFR 1.361 and 21 CFR 1.363. Under these provisions, any existing relevant records must be made available to FDA as soon as possible, not to

exceed 24 hours from the time of request, if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. If a transporter can reasonably expect that some or all of its cargo may become food contact substances, then that transporter must ensure that it has the capability to provide access within the specified time limit to records it normally maintains as a matter of business practice and that may be within the scope of a records access request by FDA.

8.3 Q: Does a firm that collects reusable containers after use and then releases them to another firm that places food in the containers, such as a bottling firm that refills the bottles with water, have to establish and maintain records under this regulation?

A: No. 21 CFR 1.327(k) provides that all persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts food and do not themselves place the food in contact with the container are excluded from the requirements of this regulation, except 21 CFR 1.361 and 1.363. However, the firm placing food in contact with the reusable containers does have to establish and maintain records of the received containers that identify the first firm that is collecting the reusable containers as the nontransporter immediate previous source.

9. Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Samples

9.1 Q: Samples are employed in a wide variety of ways within the business community and move between facilities in many ways, based largely on how many samples are involved. Larger quantities of samples are more likely to be mailed, shipped by a shipping service, or shipped by a carrier. Smaller quantities of samples are more likely to be hand carried, transported in an employee's personal vehicle, or even moved by taxi cab. Do businesses have to establish and maintain records for all samples, regardless of use or mode of transport?

A: Yes. As discussed in the response to comment 32 of the Final Rule preamble, food samples intended for consumption (including consumption via test marketing, tasting at trade shows, and promotional marketing) are subject to this regulation. Accordingly, records must be established and maintained identifying the immediate previous sources and immediate subsequent recipients of the samples in accordance with 21 CFR 1.337 and 1.345. However, 21 CFR 1.327(d) excludes persons who distribute food directly to consumers from the requirements in 21 CFR 1.345 to establish and maintain records to identify the nontransporter and transporter subsequent recipients as to those transactions. In accordance with this subsection, a firm does not need to establish and maintain records for release of samples as long as the samples are released directly to an individual consumer. For the purpose of this regulation, FDA considers a company that transfers food samples to its own employees for personal consumption to be distributing food directly to consumers as specified in 21 CFR 1.327(d). Conversely, distribution of samples and other feed to a farm that is raising animals for food or distribution of samples and other feed to contract farms is not considered to be releasing food directly to consumers. In addition and as discussed in the response to comment 70 of the Final Rule preamble, a person (including an individual partnership, corporation, or association) who distributes or receives food for purposes other than transportation is not a transporter, even if the person also transports food. Therefore, if samples are transported by an employee of either the manufacturer or recipient firm, the transporter

records specified by 21 CFR 1.352 are not required and only those records required of non-transporters are required.

9.2 Q: A firm manufactures metal and plastic closures for food products. The firm's research and development laboratory may receive food packed by a customer for performance testing by the laboratory. Excess food packages are distributed to the firm's employees at no charge. Is the laboratory subject to this regulation?

A: Yes. The laboratory must establish and maintain records of the receipt of food (including samples of food) if that food will be consumed, in accordance with 21 CFR 1.337. However, 21 CFR 1.327(d) excludes persons who distribute food directly to consumers from the requirements in 21 CFR 1.345 to establish and maintain records of the nontransporter and transporter immediate subsequent recipients as to those transactions. For the purpose of this regulation, a company that transfers food samples to its own employees for personal consumption is considered to be distributing food directly to consumers as specified in 21 CFR 1.327(d).

9.3 Q: Customers frequently ask manufacturers for laboratory samples of food ingredients for evaluation. It is unknown whether the company requesting samples will produce an edible food product. Must records be established and maintained for transfer of the samples sent to these immediate subsequent recipients?

A: As discussed in the response to comment 32 of the Final Rule preamble, food samples intended for consumption (including consumption via test marketing, tasting at trade shows, and promotional marketing) are subject to this regulation. Records must be established and maintained if there is a reasonable expectation that the ingredient samples will be used in a food product that will be consumed. If it is unclear whether the samples will be incorporated into food that is consumed, the ingredient manufacturer may wish to obtain this information from the recipient as a matter of business practice.

9.4 Q: If samples are intended for consumption by a laboratory animal (e.g., a rat) are they exempt from this regulation?

A: FDA intends to consider exercising enforcement discretion with regard to records for samples if the samples are consumed by animals that: (1) are used for research purposes only, (2) are not used for food, and (3) remain under the control of the laboratory.

9.5 Q: A supermarket headquarters building receives samples that are tested. The testing may include tasting. Is recordkeeping required to track receipt of these samples?

A: Yes. If samples will be consumed by humans for testing purposes after receipt, the firm must establish and maintain records of the nontransporter and transporter immediate previous sources of the samples as required by 21 CFR 1.337.

9.6 Q: If a manufacturing firm provides one or two samples of an item to a buyer for a retail firm for immediate consumption by that buyer, does this regulation require recordkeeping?

A: In general, yes. The manufacturing firm must establish and maintain records of the immediate subsequent recipient of the samples as required by 21 CFR 1.345.

However, if the transfer occurs in a venue where commercial buyers and members of the general public are both present and a specific recipient cannot be readily distinguished as belonging to one or the other of those groups (e.g., at a trade show open to both industry and the public where a buyer consumes one or two samples and does not provide his or her corporate affiliation or otherwise establish commercial contact), FDA intends to consider exercising enforcement discretion regarding establishment of records of that specific transfer.

9.7 Q: A research and development laboratory creates samples and ships them to a customer who consumes them. Does the laboratory have to establish and maintain records of incoming ingredients and outgoing samples?

A: Yes. The laboratory must establish and maintain records of incoming ingredients intended for use in samples that will be consumed, including records of the transporter and nontransporter immediate previous sources, as specified by 21 CFR 1.337. The laboratory must also establish and maintain records of outgoing samples that will be consumed, including records of the transporter and nontransporter subsequent recipients, as specified in 21 CFR 1.345, unless the recipients are individual consumers. For the purpose of this regulation, a company that transfers food samples to its own employees for personal consumption is considered to be distributing food directly to consumers as specified in 21 CFR 1.327(d).

9.8 Q: If one firm engages a second firm to place samples in different geographic locations that are then given to consumers for testing, what records need to be maintained?

A: As discussed in the response to comment 32 of the Final Rule preamble, food samples intended for consumption (including consumption via test marketing and promotional marketing) are subject to this regulation. Therefore, both firms must establish and maintain records with respect to the transfer of samples between them, in accordance with 21 CFR 1.337 and 1.345. However, 21 CFR 1.327(d) excludes persons who distribute food directly to consumers from the requirements in 21 CFR 1.345 to establish and maintain records to identify the nontransporter and transporter subsequent recipients as to those transactions. Therefore, the second firm need not establish and maintain records of release of the samples if they are distributed directly to individual consumers.

10. Persons Who Distribute Food Directly to Consumers

10.1 Q: A combined airline and caterer receives foods and food ingredients with production codes and expiration dates. Is the company expected to track each product by code number through the kitchen to the customer? For example, if the company receives a gallon of olive oil, must that oil be linked to each recipe where it is used and through the facility to the customer by lot number?

A: No. In general, as discussed in the response to comment 76 in the Final Rule preamble, a caterer for interstate conveyances does not qualify for the restaurant exemption defined in 21 CFR 1.328 and must comply with both 21 CFR 1.337 and 1.345. Records established and maintained in accordance with 21 CFR 1.345 must include the information reasonably available to the caterer to identify the specific source of each ingredient used to make every lot of finished product. However, an airline that caters its own flights is vertically integrated (as long as ownership of the two companies

is the same and the food is not transported independently). As discussed in the response to comment 13 of the Final Rule preamble, a vertically integrated company does not have to establish records of internal transfers of food. In accordance with 21 CFR 1.327(d), the airline is also excluded from the requirement to establish and maintain records of the immediate subsequent recipient when the food is ultimately released because it is being distributed directly to the consumer. However, if the airline were to prepare finished food products and sell them to another airline, the firm would be required to establish and maintain records for each food released to the other airline, including both the specific source of each ingredient used to make every lot of the finished food product (to the extent that the information is reasonably available) and lot numbers or other identifiers (to the extent they exist).

10.2 Q: A bottled water company delivers to businesses, and the water is consumed by employees at these businesses. Is this considered delivery to consumers with respect to recordkeeping obligations?

A: No. 21 CFR 1.327(d) only excludes persons who distribute food directly to individual consumers from the requirements in 21 CFR 1.345 to establish and maintain records. This subsection expressly states that the "term 'consumers' does not include businesses." Therefore, the bottled water company is required to establish and maintain records of its water deliveries to businesses. The exemption in 21 CFR 1.327(n) for persons who receive or hold food on behalf of specific individual consumers is not applicable because in this case the business is the purchaser and a party to the transaction with the bottled water company, and is not simply holding the bottled water for a consumer purchaser.

C. Definitions (Section 1.328)

11. General Questions (Reserved)

12. Person (Reserved)

13. Farm

FDA has addressed questions we received on this issue in the Final Rule.

14. Food

FDA has addressed questions we received on this issue in the Final Rule.

15. Manufacturing/Processing (Reserved)

16. Nontransporter

FDA has addressed questions we received on this issue in the Final Rule.

17. Nontransporter Immediate Previous Source

17.1 Q: A firm receives foreign products in an overseas container and processes them on behalf of the owner, the importer of record. Who is the immediate previous source? What if the importer of record considers the source of the product confidential commercial information?

A: 21 CFR 1.328 defines a nontransporter as a person who owns food *or* who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. Section 1.328 defines a "nontransporter immediate previous source" as a person that last had food before transferring it to another nontransporter and "person" as including an individual, partnership, corporation, and association. In the above example, both the owner of the food and the firm receiving the food are nontransporters subject to the final rule. Both are responsible for complying with the rule, which either may do for the other as a matter of business practice, but legal responsibility remains with both parties. The nontransporter immediate previous source is the foreign nontransporter that released the food to the owner and receiving firm, whether or not this information is confidential. Again, as a matter of business practice, the receiving firm and/or owner may choose to arrange to have another establish and maintain records on their behalf at the location where the food is received or at a reasonably accessible location that contains the confidential information, but legal responsibility for providing the records, including information that the importer of record considers confidential, within the timeframes specified in 21 CFR 1.361 remains with the owner and receiving firm.

17.2 Q: Who is the nontransporter immediate previous source of an imported food? When an imported food arrives at the port of entry, the importer of record is responsible for finding an appropriate place to store the food. If, for example, the importer places the food in a contract warehouse at the port of entry and that warehouse is owned by Company A but leased to Company B, it is not clear which company (the importer, Company A, or Company B) should be considered the nontransporter immediate previous source with respect to the next recipient. It seems the answer should not depend on who owns the warehouse. Since the importer of record is legally responsible for the food for Customs purposes, shouldn't the importer of record be the nontransporter immediate previous source?

A: The response to comment 17 of the Final Rule preamble notes that this regulation apply to persons who manufacture, process, pack, transport, distribute, *receive*, *hold*, or *import* food in the United States, unless the person qualifies for an exclusion in 21 CFR 1.327. An importer of record or an initial United States recipient that is involved in one or more of the identified activities must establish and maintain the required records for the imported food. In this case, the imported food is received and held in a warehouse. If Company B has dedicated use and physical control of the warehouse, then the imported food is in Company B's physical possession. If Company A retains physical control of the leased warehouse, then the imported food is in Company A's possession. Section 1.328 defines a nontransporter as a person who *owns* food *or* who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. The importer of record and the entity with physical possession of the food (Company B or Company A) are considered nontransporters by this definition. If the owner of the imported food is not the importer of record, then that owner is also considered a nontransporter. Section 1.328 defines a "nontransporter immediate previous source" as a person that last had food before transferring it to another nontransporter and "person" as including an individual,

partnership, corporation, and association. In the above example, the importer of record, the person with physical possession of the food, and the owner (if a third party) are all nontransporters subject to the final rule. All are responsible for complying with the rule, which one may do for the other as a matter of business practice, but *legal* responsibility for establishment and maintenance of records and for meeting the records access timeframes specified in 21 CFR 1.361 remains with all parties. If the food is further delivered from the warehouse, the recipient's nontransporter immediate previous source is whichever company (A or B) had physical control over the warehouse.

17.3 Q: A nontransporter firm may receive a product from a vendor with multiple ship points. Currently the firm's systems cannot record the ship point. Is the firm required to record the actual ship point as the nontransporter immediate previous source, or just the contact information for the vendor?

A: 21 CFR 1.337(a)(1) requires a nontransporter to establish and maintain records for all food it receives that identify the name of the firm, address, telephone number and, if available, the fax number and email address of the nontransporter immediate previous source. Section 1.328 defines "nontransporter immediate previous source" as a person that last had food before transferring it to another nontransporter and "person" as including an individual, partnership, corporation, and association. Therefore, the nontransporter firm above must provide the specific address and other contact information of the legal person (the vendor) that released the food to them but does not need to provide information regarding particular ship points of the vendor.

17.4 Q: A supermarket receives direct store deliveries from various companies. For some of these companies, the actual product is manufactured by a franchisee or contractor. From a recordkeeping standpoint, is the nontransporter immediate previous source the brand company or the contractor?

A: 21 CFR 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. Section 1.328 defines a "nontransporter immediate previous source" as a person that last had food before transferring it to another nontransporter and "person" as including an individual, partnership, corporation, and association. A person who enters into a contract to hold, manufacture, process, pack, import, receive, or distribute food is considered a nontransporter, even if that person subcontracts the actual performance of the covered action to another entity. In the above example, both the brand company and the actual manufacturer are nontransporters subject to the final rule. Both are responsible for complying with the rule, which either may do for the other as a matter of business practice, but legal responsibility for establishment and maintenance of records and for meeting the records access timeframes specified in 21 CFR 1.361 remains with both parties. The supermarket may identify either the brand company or the manufacturer as its nontransporter immediate previous source.

18. Nontransporter Immediate Subsequent Recipient

FDA has addressed questions we received on this issue in the Final Rule.

19. Perishable Food (Reserved)

20. Recipe (Reserved)

21. Restaurant

FDA has addressed questions we received on this issue in the Final Rule.

22. Retail Facility

FDA has addressed questions we received on this issue in the Final Rule.

23. Transporter

FDA has addressed questions we received on this issue in the Final Rule.

24. Transporter's Immediate Previous Source

FDA has addressed questions we received on this issue in the Final Rule.

25. Transporter's Immediate Subsequent Recipient

FDA has addressed questions we received on this issue in the Final Rule.

D. Do Other Statutory Provisions and Regulations Apply? (Section 1.329)

26. General Questions (Reserved)

E. Can Existing Records Satisfy the Requirements of this Rule? (Section 1.330)

27. General Questions

FDA has addressed questions we received on this issue in the Final Rule.

F. What Information is Required in the Records You Must Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Source and Immediate Subsequent Recipients? (Sections 1.337 and 1.345)

28. General Questions (Reserved)

29. Information Reasonably Available to Identify the Specific Source of Each Ingredient

29.1 Q: A bulk grain elevator receives many small lots from individual farmers, aggregates them, and blends them to whatever specifications are required. What records and degree of lot specificity are required for the grain elevator?

A: The grain elevator is required to establish and maintain records for each incoming shipment of grain, including a lot number if it exists, in accordance with 21 CFR 1.337. When blended grain is released by the facility, it must also establish and maintain a record, including both the lot number if one is assigned and information to identify the specific source of each component grain, to the extent that the information is reasonably available, in accordance with 21 CFR 1.345. In the response to comment 94 in the Final Rule preamble, FDA acknowledges that the degree of specificity may be limited by the current physical configuration of the facility. For example, the facility may place thirty lots from farmers into a single storage bin, place another thirty lots into a second bin, and draw from both bins to create a blended product that is transferred to an immediate subsequent recipient. The record created for the outgoing blended product should indicate all immediate previous sources for the component grain; in this example there may be as many as sixty.

29.2 Q: A feed mill receives ingredients and commingles individual shipments into bins which are never completely empty. Over the course of a year, a hundred or more lots could theoretically be part of any food drawn from a bin. Would the feed mill have to provide all these lot numbers for food it releases?

A: Yes. Manufacturers are required to establish and maintain records for each food received, including the lot number if it exists, in accordance with 21 CFR 1.337. When a food is released by a manufacturer, the firm must establish and maintain records that include information reasonably available to identify the specific source of each ingredient used to make every lot of finished product in accordance with 21 CFR 1.345. In the response to comment 94 in the Final Rule preamble, FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with specificity to the outgoing product, and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. Because shipments of incoming material are commingled in the storage bin, the record created for every lot of food released by the manufacturer that incorporates material from the bin would include all possible sources of the material placed in that bin.

29.3 Q: A firm uses raw agricultural commodities to manufacture its products. What are the recordkeeping requirements: (1) if the firm receives its ingredients directly from farms and commingles them in storage bins on site, and (2) if the firm receives ingredients that already have been commingled by a distributor?

A: The source of each shipment that enters a particular storage bin must be recorded in accordance with 21 CFR 1.337. If the commodities are commingled on site, there will be more sources for a given bin. In both cases, incoming sources of ingredients must be linked to finished products leaving the site to the extent that the information is reasonably available in accordance with 21 CFR 1.345. For example, if a lot of a product incorporated an ingredient from a particular bin and that bin was filled with a commodity derived from five immediate previous sources, then those five sources would be the reasonably available information for that ingredient. If the bin was refilled before being emptied and now may contain ingredients from up to ten immediate previous sources, then this is the information that is reasonably available. If the firm receives ingredients that already have been commingled by a distributor, the firm only has to record the lot numbers of the food, as received, to the extent that information exists, and link incoming sources of ingredients to finished products leaving the site to the extent that the information is reasonably available in accordance with 21 CFR 1.345.

29.4 Q: A manufacturing firm may handle over a thousand different ingredients on the same day, and three or four lot codes of the same ingredient from the same supplier may be used on a particular day. Assuming the ingredients arrive at the manufacturing facility with lot codes, does the manufacturer have to track each lot code and link it to a finished product?

A: Yes. The manufacturer is required by 21 CFR 1.337(a)(4) to establish and maintain records for each ingredient it receives, including the lot codes of each ingredient received if they exist. When the manufacturer releases a food, it must also establish and maintain records for that food. The records must include both the lot code of the finished product if it exists and the specific source of each ingredient used to make every lot of finished product, to the extent that information is reasonably available, as required by 21 CFR 1.345(b).

29.5 Q: A firm manufactures many varieties of ice cream and sorbet, and delivers these products directly to restaurants and scoop shops. Do the incoming sources (including lot codes) of each ingredient have to be linked to the specific outgoing products?

A: Yes. As a manufacturer, the firm must establish and maintain records for the ingredients that it receives, including lot codes if that information exists, in accordance with 21 CFR 1.337. The firm must also establish and maintain records when it releases each article of food, including information reasonably available to identify the specific source of each ingredient in every lot of ice cream or sorbet, in accordance with 21 CFR 1.345.

29.6 Q: A manufacturing firm has multiple suppliers of particular ingredients and packaging materials. Is it sufficient to simply record all the potential suppliers that an ingredient or packaging material might have come from?

A: Persons who manufacture, process, or pack food are required to establish and maintain records regarding receipt of the lot or code number or other identifier of each ingredient and any finished container that they place in contact with food, if a lot or code number or other identifier exists, in accordance with 21 CFR 1.337 and 1.327(k). When the food is released, records must be established and maintained that include the specific source of each ingredient used to make every lot of finished food and any finished container placed in contact with food, to the extent that the information is reasonably available (e.g., does not require physical reconfiguration of the manufacturing facility), in accordance with 21 CFR 1.345. "Packaging" is defined in 21 CFR 1.328 as "the outer packaging of food that bears the label and does not contact the food." The manufacturer, processor, or packer does not have to establish and maintain records for any packaging or for finished containers that it does not place in contact with the finished food, as stated in 21 CFR 1.327(j). All existing relevant records must be made available as soon as possible to FDA on request, not to exceed 24 hours, as required by 21 CFR 1.361 and 1.363, if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. If information is reasonably available when food is released to narrow the possible sources of an ingredient, it is not sufficient to record all potential suppliers that an ingredient or packaging material *might* have come from if there is no expectation that that supplier's product would be in the finished product (e.g., no shipments have been received from a vendor for months and onsite supply has been depleted).

29.7 Q: A candy manufacturer has a starch molding operation in which a candy is deposited into a starch that has impressions. The starch is used to form the candy and remove the moisture. After a period of time the candy is removed from the starch and sent to packaging. The starch is dried, cooled and placed back into the starch trays for the deposit of more candy. In the manufacturing operation some starch is lost due to spillage and dusting. New starch is added to replace the lost starch. It is possible that the starch in the system could have been in the system for many months. The manufacturer only replaces 300-400 pounds a day and the entire system has over 40,000 pounds. How should the company track this?

A: FDA considers the starch a food ingredient, as defined and discussed in the response to comment 61 in the Final Rule preamble. However, 21 CFR 1.345(b) only requires nontransporters to identify the specific source of each ingredient that was used to make every lot of finished product to the extent that such information is reasonably available. In this case, information about the source of starch from which daily additions to the system are made should be reasonably available, and thus it should be possible to define a length of time (and series of lots of candy) during which a specific source of starch is being used to replenish the supply. Depending on the size of each lot of starch relative to the size of the entire system and the number of suppliers, the manufacturer might reasonably identify multiple sources of starch that contribute to the system. The manufacturer would not need to identify sources of starch received prior to the compliance date established in the Final Rule.

29.8 Q: A bottling firm that bottles water and delivers it to various consumers receives returned bottles for reuse from these customers. Does this regulation require that the outgoing refilled bottles that are released by the bottling manufacturing firm must be linked to the source of the incoming bottles returned by the firm's customers (i.e., the individual consumers)? Does the bottling firm have to record the lot numbers or other identifiers of the empty bottles collected from these customers?

A: 21 CFR 1.337 requires that nontransporters identify the immediate previous source of all food received. Section 1.327(k) states that persons who place food directly in contact with the finished container must establish and maintain records for the packaging. When the bottling firm receives new bottles from the bottle manufacturer for first time use, the record of receipt must include the lot or code number or other identifier (if it exists) as required by 21 CFR 1.337(a)(4). When bottled water is released to businesses (but not individual consumers), 21 CFR 1.345(b) requires the nontransporter who releases that food to establish and maintain records that include information reasonably available to identify the specific source of every ingredient used to make every lot of finished product. This includes the specific source of the finished container that contacts the food (e.g., bottle) if the nontransporter is the one who placed the finished food (e.g., water) in contact with the finished container. When the firm receives returned bottles from customers, the response to comment 21 in the Final Rule preamble states that the immediate previous source for returned water bottles is the customer. FDA intends to consider exercising enforcement discretion with regard to the name of the specific customer who returned each empty bottle if the bottling company establishes records when used empty bottles are received from multiple customers (businesses or individual consumers) indicating "customer return" or equivalent as the source, provided the bottles are returned as is (i.e., without further manufacturing/processing, such as cleaning, by a third party). When the bottles are

refilled and released to customers, FDA intends to consider exercising enforcement discretion with regard to 21 CFR 1.345(b) if the records indicating the source of the incoming returned bottles indicate "customer returns." If, however, a third party firm collects reusable containers after use from customers (in this example empty water bottles), and then releases them to the manufacturing firm that refills them, FDA does not intend to consider exercising enforcement discretion regarding the manufacturing firm's (in this example, the bottling company's) immediate previous source of the reusable containers. After reusable bottles are used for the first time, FDA intends to consider exercising enforcement discretion regarding the requirement in 21 CFR 1.337(a)(4) for lot numbers or other identifiers.

30. Adequate Description of Type of Food

30.1 Q: A warehouse receives imported food that is stored in shipping containers. Upon receipt, the warehouse only records the container numbers of the containers it receives and holds. Is this sufficient information?

A: A person, such as the warehouse above, who manufactures, processes, packs, distributes, receives, holds, or imports food must be able to provide to FDA records containing sufficient information to satisfy the requirements of 21 CFR 1.337 and 1.345 as soon as possible upon request, not to exceed 24 hours, as specified by 21 CFR 1.361 and 1.363. Records that only list the container number do not contain sufficient information to meet the requirements for an adequate description of the food, its quantity, and how the food is packaged.

30.2 Q: How much detail is required in describing a food (e.g., different types of commodity grains, different varieties of a particular grain)?

A: Descriptions of commodity grains and produce must be as specific as possible (e.g., Roma tomatoes versus cherry tomatoes, sweet corn versus feed corn), as required by 21 CFR 1.337 and 1.345. As discussed in the response to comment 64 in the Final Rule preamble, this type of description saves time and resources during a tracing investigation because it allows FDA to narrow its focus to the appropriate product during the investigation.

30.3 Q: Many food manufacturing/processing facilities have storage vessels in which out-of-specification, outdated, returned and/or damaged food products are commingled and stored pending transfer to animal farming operations where the commingled products are used as animal feed or are otherwise reprocessed into an ingredient used in animal/pet food products. The composition of the contents of the storage vessel varies from day to day in terms of the products and quantities. Lot codes of product transferred to the storage vessel and the specific products themselves and their quantities are not recorded and it would be burdensome to do so. Is the food processor or manufacturer required to establish and maintain records of the food released to farms or reprocessors for use as animal feed that include the specific products, quantities and lot codes of the immediate previous sources of the contents (or ingredients) in the storage vessel?

A: As discussed in the answer to Question 1.6 above, FDA intends to consider exercising enforcement discretion regarding establishment 1of records by food manufacturing/processing facilities for food waste or byproducts they release to farms that is fed directly to animals without further manufacturing/processing. If food manufacturing/processing facilities release food that is processed further prior to

consumption by animals, FDA does not intend to consider exercising enforcement discretion regarding sections 1.345(a)(1), (3) and (6). However, FDA intends to consider exercising enforcement discretion regarding 21 CFR 1.345(a)(2), (4), (5) and (b) if the food being released is appropriately described as 'facility waste' or by reference to all the substances in production during a specific time period in lieu of identifying the specific source of each ingredient used to make every lot of finished product.

31. Date Food Received or Released

FDA has addressed questions we received on this issue in the Final Rule.

32. Lot or Code Number/Other Identifier

32.1 Q: A food processor records the lot codes on pallets of food, which are then delivered to customers by truck. Currently, the processor does not link lot codes with specific customers. Is this required by this regulation?

A: Yes. Persons who manufacture, process, or pack food are required by 21 CFR 1.345 to identify the lot or code number or other identifier of the food that they release to each immediate subsequent transporter and nontransporter recipient, if that information exists. If there is a lot code on both the pallet and the food, and only the lot code of the pallet is recorded, the processor must be able to link each pallet to the lots of food it contains. However, as discussed in the response to comment 112 in the Final Rule preamble, food placed directly on the shelves of a retail store by a manufacturer, processor, or packer upon delivery (direct store delivery) is excluded from the requirement to record lot or code numbers.

32.2 Q: If a manufacturer receives ingredients that have a lot number but that lot number is not provided to the manufacturer by the ingredient supplier, is the manufacturer required to actively obtain the lot number for each ingredient?

A: Yes. 21 CFR 1.337 requires that persons who manufacture, process, or pack food must establish and maintain records that include the lot or code number or other identifier for all food they receive, if that information exists. The manufacturer must obtain the lot numbers for each ingredient received from the ingredient supplier.

32.3 Q: A company owns retail stores and receives multiple shipments of the same item into its stores. Currently, the company would be able to identify all of the transporters that delivered a specific product to a particular store over the last several months. However, the company could not identify the specific transporter who delivered a particular lot to that store. For example, the company's records would show that on a given date, ABC Trucking Company delivered 25 cases of Brand X 1.2oz chocolate bars to a specific store. However, the company could not link a specific box of those bars on the store shelf to a specific carrier, because there were other deliveries of that item from other carriers on other dates, and those chocolate bars are now commingled on the shelf. Would the company's current capabilities be in compliance with this regulation?

A: 21 CFR 1.337 requires that nontransporters establish and maintain records that identify the transporter and nontransporter immediate previous sources for all food they receive. Only persons who manufacture, process, or pack food are required by 21 CFR 1.337(a)(4) to include lot or code numbers or other identifiers in the records they

establish and maintain, if the information exists. Therefore, a retail store receiving 25 cases of Brand X chocolate bars must create at the time of receipt a record that includes the specific transporter and nontransporter sources of the food, an adequate description of the food, the date of receipt, the quantity of food, and how the food is packaged. The record does not have to include the lot or code number or other identifier of the product.

32.4 Q: If a firm is a manufacturer, processor, and packer of a single product, would all lot numbers associated with this process (e.g., lot numbers for individual cans, lot numbers for pallets, etc) have to be tracked?

A: 21 CFR 1.345 requires persons who manufacture, process, or pack food to establish and maintain records when releasing the food to another person that include the lot or code number or other identifier (to the extent this information exists). FDA recommends that a vertically integrated company which generates several lot or code numbers or other identifiers in the course of its operations use the most specific one. As explained in the preamble to the Final Rule, more specific information about the food helps FDA narrow its investigation and increase the speed of the trace in the event that there is a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. However, another acceptable alternative would be for the firm to record identifiers of larger packages (such as pallets) but retain the ability to link these to lots of cans when necessary.

33. Quantity and How the Food is Packaged

FDA has addressed questions we received on this issue in the Final Rule.

34. Name, Address, Telephone Number, Fax Number, E-Mail Address of Transporters Who Transported the Food To You and From You

34.1 Q: A manufacturer loads a container that is being exported via ocean freight out of the United States. The ocean carrier contracted by the manufacturer is responsible for handling the inland drayage from the manufacturer to the port. For the purpose of this regulation, is the manufacturer's transporter immediate subsequent recipient the ocean carrier or the drayage company that is subcontracted by the ocean carrier?

A: 21 CFR 1.345(a)(6) defines the transporter immediate subsequent recipient as the transporter who transported the food from the nontransporter. In this case, the manufacturer may identify the transporter immediate subsequent recipient as either the ocean carrier with whom they contracted or the drayage company that directly receives the container from the manufacturer. Either choice complies with the requirements of 21 CFR 1.345(a)(6).

34.2 Q: A nontransporter firm contracts with an ocean carrier to bring imported food to the firm's facility. The ocean carrier subcontracts with a trucking firm to transport the food from the port to the facility. Who is the transporter immediate previous source for the firm?

A: 21 CFR 1.337(a)(6) defines the transporter immediate previous source as the transporters who transported the food to the nontransporter. In the example given above, the nontransporter firm may identify the transporter immediate previous source for the food as either the ocean carrier with whom they contracted or the trucking firm who

physically delivers the food to the firm's facility. Either choice complies with the requirements of 21 CFR 1.337(a)(6).

34.3 Q: What are the manufacturer's and transporter's recordkeeping obligations for a food product that is transported intracompany by a contract transporter? For example, a manufacturing firm may contract with a transporter to move food product, intracompany, from its manufacturing facility to its distribution center.

A: 21 CFR 1.345 requires that persons who manufacture, process, pack, distribute, receive, hold, or import food establish and maintain records whenever they release food to another person. As discussed in the responses to comments 13 and 71 in the Final Rule preamble, intracompany transfer of food is not subject to additional recordkeeping requirements, provided that the food is not released to another person. In this example, the manufacturing firm temporarily releases the food to another entity (person), the contract transporter. The manufacturing firm would be required to establish and maintain records of the transfer of food (including lot numbers if they exist) from the facility to the transporter and nontransporter (the distribution center) immediate subsequent recipients.

34.4 Q: Transporters may deal with brokers who only provide a location and time to pick up a product, but do not provide other contact information. Does this regulation require a transporter to identify contact and other information for the nontransporter immediate previous source, or can the broker be used as the immediate previous source?

A: This regulation provides transporters multiple options to comply with the records requirements for each article of food transported. The information required by the Department of Transportation and described in 21 CFR 1.352(b) or 1.352(c) will satisfy the requirements of this regulation, as will information meeting the requirements of the Warsaw convention under 21 CFR 1.352(d). The transporter likely already has this information. The transporter may also meet its obligation by complying with 21 CFR 1.352(a) (identifying specific information that must be kept) or 21 CFR 1.352(e) (providing for the transporter to enter into an agreement with the nontransporter immediate previous source) but if the broker is not considered the immediate previous source than these options require the transporter to obtain information in addition to the broker and location and time of pick up. Whether the broker is considered an immediate previous source as defined in 21 CFR 1.328 depends on the broker's role, as discussed in response to Question 1.1.

34.5 Q: A warehouse has information about the brokers who arrange deliveries and releases of food products, but not about the actual contract drivers and trucks that transport the products. Is this information required under this regulation?

A: No. 21 CFR 1.328 defines a transporter as someone who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food. For the purpose of this regulation, FDA considers a transporter to include a person who enters into a contract to transport food, even if that action is subsequently subcontracted to another entity. In this case, the warehouse may identify as their transporter immediate previous source or immediate subsequent recipient either the freight broker or the contract driver in compliance with 21 CFR 1.337(a)(6) and 1.345(a)(6).

34.6 Q: Some items that arrive at a distribution center from an independent supplier are cross-docked. In other words, they are not formally received at the warehouse, but transferred to a company-owned truck for delivery to one of the company's stores. For these items, no detailed item records are kept in the distribution center and we do not currently have a mechanism in place for identifying the transporter immediate previous source. The store invoice for the goods from the supplier is the only timely method to acquire the supplier immediate previous source, although there is not a current software solution for this. However, this invoice does not identify the transporter immediate previous source that brought the goods to the warehouse. Can the company use the invoice from the supplier to the store as a track-back document? The supplier should be able to identify their transporter immediate subsequent recipient (the company's transporter immediate previous source).

A: No, in most circumstances. The recordkeeping requirements in 21 CFR 1.337 and 1.345 of this final rule apply to persons who "hold" food for purposes other than transportation. As defined in 21 CFR 1.328 and explained further in the response to Comment 20 in the preamble to the Final Rule, "holding" means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. In the above example, if the distribution center is a warehouse, then it must establish and maintain records that identify the immediate previous source of the food received (the independent supplier) and the transporter that brought the food to it, as required by 21 CFR 1.337, as well as the records required by 21 CFR 1.345. It cannot simply rely upon the invoice, because the invoice does not identify the transporter. In the rare circumstance that an independent facility, most likely a truck terminal, merely provides a location for trucks to transfer possession, custody, or control to another entity and does not itself take possession, custody, or control, even briefly (e.g., the terminal provides a location for one truck to transfer goods directly to another truck when both trucks are present at the terminal at the same time), then the independent facility is not subject to these regulations. If the facility is not independent but instead is owned by a transporter, then the transporter must maintain records that include the identity of the person from whom the transporter received the food, the person to whom the transporter delivered the food, and the route of movement of the food, which will include the terminal, as required by 21 CFR 1.352(a) or 21 CFR 1.352(b), depending on which option the transporter selects for compliance.

35. Vertically Integrated Companies

35.1 Q: If Company Z owns Facilities 1, 2 and 3, must it also own the trucks that transfer product from Facility 1 to Facility 2 and from Facility 2 to Facility 3 in order to be considered a vertically integrated company?

A: Yes. A vertically integrated company, as described in the responses to comments 13 and 71 in the Final Rule preamble, is defined by continuous possession of an article of food. Once a covered person receives food and keeps information on its immediate previous source, that person does not need to keep additional records until it releases the food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. Therefore a company is no longer integrated if the food passes out of its control and is released to another person before returning to the company's possession. For example, if an independent transporter takes possession of the food in order to transport it between two facilities owned by the same company, the company must establish and maintain records identifying the transporter and nontransporter immediate previous sources and immediate subsequent recipients.

35.2 Q: Does mode of transportation matter in cases of vertically integrated companies?

A: No. A vertically integrated company, as described in the responses to comments 13 and 71 in the Final Rule preamble, is defined by continuous possession of an article of food rather than its mode of transport. A person or company must establish and maintain records whenever it releases the food to another person or company, including a transporter.

35.3 Q: If a nontransporter has a transporter subsidiary and uses that subsidiary to transport food to others, is the transfer from the nontransporter to the transporter subsidiary considered an internal transfer?

A: No. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. A subsidiary is a distinct legal person and records of the transfer of possession from the nontransporter to the transporter subsidiary must be established and maintained.

35.4 Q: Are two corporate entities part of the same vertically integrated company if they have the same controlling parent?

A: No. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. If the two corporate entities are legally distinct persons, they are not considered part of the same vertically integrated company, and records of transfers of food between them must be established and maintained.

35.5 Q: If subsidiaries are legally distinct but are managed operationally as a single entity, are they a single entity for the purpose of this regulation?

A: No. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. The exemption for vertically integrated companies only applies to distinct legal persons.

35.6 Q: A grain testing company operates on its customer's property. The customer owns the facilities, but testing company employees sample grain trucks and rail cars and then perform grade testing while the truck or rail car waits. Some of the sample is destroyed by the test. The rest of the sample is collected in a grain wagon owned by the customer. Once the wagon is full, the testing company sells the grain back to the customer. Is the testing company exempt from this regulation?

A: No. 21 CFR 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. Although in this case the testing operation occurs within the customer's facility and the sampled grain never leaves the site, the grain testing company has ownership of the sampled grain and sells it back to the customer. This

would be considered release of the food to another person and both companies must establish and maintain records of this transfer as required by 21 CFR 1.337 and 1.345.

35.7 Q: Does a franchisor's warehouse that delivers to a franchisee's store comprise a vertically integrated operation?

A: No. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. The franchisee's store is a legally distinct person and records of movement of food products from warehouse to franchise store must be established and maintained. If the franchise store is a restaurant, the franchise store does not need to establish and maintain records because restaurants are exempt from all requirements in accordance with 21 CFR 1.327(b).

35.8 Q: A retail grocery store chain contracts exclusively with a wholesale company for distribution. Does that wholesaler, under specific contract, have to track to which stores the particular product went?

A: Yes. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. The wholesaler is required to establish and maintain records of the movement of food to the warehouse in accordance with 21 CFR 1.337 and from the warehouse to the grocery stores in accordance with 21 CFR 1.345, because it is releasing food to another legal person. The retailer is required to establish and maintain records of the receipt of food in accordance with 21 CFR 1.337.

35.9 Q: If a vertically integrated manufacturer, packager, and distributor contracts with a second firm for dedicated use of the second firm's warehouse, would this qualify as a being vertically integrated? In this case the first firm may have control of the warehouse but not ownership of the warehouse.

A: Yes. A vertically integrated company, as described in the responses to comments 13 and 71 in the Final Rule preamble, is defined by continuous possession of an article of food. In the example above, because the integrator has "dedicated use" of the second firm's warehouse, it has retained continuous and sole possession of the food within its "person."

35.10 Q: A combined airline and caterer retrieves and reuses unused soda, coffee, peanuts, and pretzels. The company currently does not link incoming unused food products intended for reuse to outgoing ones on restocked planes. Is the company expected to trace all inbound products through recordkeeping?

A: No. As discussed in the responses to comments 13 and 71 in the Final Rule preamble, a company is vertically integrated to the extent that it does not release food to another person. Capture of unused food products from one flight and restocking on another by an airline that caters its own flights does not involve release of the food to another person. Since the products never leave the possession of the company, records do not have to be established and maintained regarding movement of the food. If the airline and caterer were distinct persons, they would be required to record any movement

of food between them in accordance with 21 CFR 1.337 and 1.345. Such records must include the immediate previous source or immediate subsequent recipient of the food, an adequate description of the food, the quantity of food, and how the food is packaged. However, records showing distribution of food to consumers are not required.

35.11 Q: Can a legal entity select a subset of facilities in the chain of custody to be a vertically integrated operation, and if so, under what conditions? For example, can legal entity "T," who manufactures, packages and distributes product "M," designate the manufacturing facility and warehouse used to store newly made inventory 10 miles away as a one vertically integrated operation but exclude 4 T-owned regional warehouses that product will be subsequently shipped though before delivered to retailers?

A: As discussed in the response to comment 13 in the Final Rule preamble, a vertically integrated operation must establish and maintain records that identify the immediate previous sources of all food it receives, but does not have to establish and maintain records identifying immediate subsequent recipients of the food until that food is released to another person (including a transporter). However, the vertically integrated operation may choose to maintain records of some or all internal transfers of food as a matter of business practice. Sections 414(a) and 704(a) of the Act provide FDA access to existing records relating to manufacture, processing, packing, transportation, distribution, receipt, holding, or importation of food when the records access requirements of the Bioterrorism Act are satisfied.

36. Reclamation Centers

36.1 Q: A supermarket chain processes food product returns through a reclamation center. Some products go from the center to donations, some back to stores in the chain, some goes back to the vendors, and some is sold to salvagers for resale. What are the recordkeeping requirements for these products?

A: As described in the response to comment 44 in the Final Rule preamble, a reclamation center owned by the supermarket chain will be treated as if it is part of the supermarket for the purpose of this regulation. The response to comment 44 also states that the release of food to nonprofit organizations is considered equivalent to direct distribution to a consumer and is exempt from recordkeeping requirements. However, if the food is returned to the manufacturer or sold to another nonconsumer, the reclamation center must establish and maintain records identifying the immediate subsequent recipient of the food, to the extent this information is reasonably available. If the reclamation center is an independent entity, then both the supermarket and the reclamation center must establish and maintain records of product movement between them. The other transactions are treated as described above.

37. Direct Store Delivery

37.1 Q: The final regulation requires persons who are manufacturers to keep production code/lot data. The final regulation also provides certain exemptions (i.e., from lot control) to persons who directly place their products into a retail establishment. For a vertically integrated company that encompasses both activities, it is not clear which requirements apply. Can such an operation maintain lot tracking from the processing/packaging facility through receipt at the last company owned distribution center prior to delivery to a retail outlet?

A: Yes. 21 CFR 1.337 and 1.345 require persons who manufacture, process, or pack food to record the lot number or other identifier of the food (to the extent this information exists) for food they receive or release, respectively. A vertically integrated company that also does direct store deliveries (DSD) is performing mixed nontransporter activities: (1) it is manufacturing, processing, packing, holding, transporting, receiving, and distributing its products; and (2) it is acting as a retailer (Retailer A) that is essentially renting shelf space from another retailer (Retailer B) when it stocks its products on Retailer B's store shelves. Accordingly, the vertically integrated company must establish and maintain records for each of these two distinct functions. As required by 21 CFR 1.337 and 1.345, the manufacturer must establish and maintain records of all food it receives, and all food it releases to its distribution or warehouse location, including lot number or other identifier (to the extent this information exists) as required by 21 CFR 1.345(a)(4). The DSD (Retailer A) must record the release of food to Retailer B as required by 21 CFR 1.345, but is not required to record lot numbers. Retailer B also is a nontransporter who is subject to these regulations because it has custody or control of the food. Accordingly, it must establish and maintain records of all food it receives from the DSD in accordance with section 1.337, but it is not required to record lot numbers, as it is not manufacturing, processing or packing the food. (*See* Question 6.1 for another example of a person performing mixed activities – in that case, an in-store bakery within a retail store.)

37.2 Q: A company manufactures a food product (e.g., a gallon of milk) and places that milk on a truck owned either by the company or by a third party for delivery to a warehouse/distribution facility. Does the company have to keep records that contain the lot or code number or other identifier of that gallon of milk (in addition to the normal immediate previous source and immediate subsequent recipient information.)? If instead the same company places the gallon of milk on a truck owned either by the company or by a third party and delivers it directly to a retail store, does the company need to keep records that contain the lot or code number or other identifier of that gallon of milk?

A: Yes. Sections 1.337 and 1.345 require persons who manufacture, process, or pack food to record the lot number or other identifier of the food (to the extent this information exists) for food they receive or release, respectively. In both examples, the company is a manufacturer that is releasing the food to another person. In the first situation, the immediate subsequent recipient is the warehouse/distributor and the transporter taking the food to the warehouse/distributor is either the manufacturer or the third party. In the second case, the release from the manufacturer is to the retailer directly. Accordingly, section 1.345(a)(4) requires the manufacturer to include the lot number or other identifier of the food *to the extent this information exists*. If the manufacturer does not provide lot numbers or other identifiers, the rule does not require it to create one. The warehouse/distributor is not required to record the lot numbers or other identifiers, even if they exist, unless it is subsequently packing (including repacking) the milk after receipt. The retailer also is not required to record the lot numbers or other identifiers, even if they exist, as it is not manufacturing, processing, or packing the milk.

G. Who is Required to Establish and Maintain Records for Tracing the Transportation of All Food? (Section 1.351)

38. General Questions

38.1 Q: There are ship owners that simply haul freight where the transporter is the owner of the container. The vessel owner is not considered the transporter; the owner of the container has the bill of lading and other information about the container's contents and destination. Does the owner of the vessel now need to establish and maintain records?

A: A transporter is defined as a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. This definition also includes a foreign person that transports food in the United States, regardless of whether the foreign person has possession, custody, or control of the food for the sole purpose of transporting the food. In the situation described above, the vessel owner has physical possession of the food container for the sole purpose of transporting the food and is considered a transporter. 21 CFR 1.352 requires that each transporter establish and maintain records that identify the immediate previous source and the immediate subsequent recipient of an article of food, regardless of whether the immediate previous source and immediate subsequent recipient are transporters or nontransporters. The relevant records must be created at the time of each transfer of the food. The transporter may enter into an agreement in which the nontransporter immediate previous source or immediate subsequent recipient establishes, maintains, or establishes and maintains, the required information as described in 21 CFR 1.352(e). The vessel owner is therefore required to establish and maintain records as specified in 21 CFR 1.352, as long as that vessel is transporting the food in the United States.

H. What Information is Required in the Transportation Records? (Section 1.352)

39. General Questions

39.1 Q: A transporter picks up a container from a pier; what information is the transporter required to have about the contents of the container?

A: The transporter must establish and maintain records that contain the information specified in 21 CFR 1.352(a), (b), (c), or (d) unless there is a pre-existing agreement with the immediate previous source or immediate subsequent recipient to establish, maintain, or establish and maintain that information as described in 21 CFR 1.352(e).

I. What Are the Record Retention Requirements? (Section 1.360)

40. General Questions

40.1 Q: A facility receives a product with two-year record retention requirement, holds it for three years, and then releases it. Is the facility required to retain the incoming records until or some time after the product is released, regardless of the holding period?

A: The facility is not required to maintain any record for longer than two years after its creation at the time of the transaction it describes, because Section 306 of the Bioterrorism Act explicitly limits the retention of records to two years or less. Records created when a food subject to the two year record retention requirement is received may be discarded after two years, even if the product remains in the facility. The facility still must establish and maintain records identifying the transporter and nontransporter

immediate subsequent recipient when the food is released in accordance with 21 CFR 1.345, even if the retention period for the record identifying the immediate previous source has expired. If a facility anticipates that it may hold food for longer than two years, it may wish to retain records of receipt for more than two years as a matter of business practice. Such records could be helpful to both the facility and FDA in the event of a trace back or trace forward investigation.

J. What Are the Record Availability Requirements? (Section 1.361)

41. General Questions

41.1 Q: The regulation requires each nontransporter to establish and maintain records onsite or at a reasonably accessible location. The recordkeeping requirements may be a burden for smaller businesses that assist in product development and product sample testing. Can a larger firm that hires a smaller one for food development and testing maintain the records on behalf of the smaller firm?

A: 21 CFR 1.360 requires each nontransporter to establish and maintain records at the location where the covered activities described in the records occurred, or at a reasonably accessible location. FDA does not intend to specify the method or system by which this is done. In this case, in the event that FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, relevant records must be made accessible onsite at the testing facility or at a reasonably accessible location as soon as possible upon request by FDA, not to exceed 24 hours, as required by 21 CFR 1.361 and 21 CFR 1.363. Regardless of the specific arrangements, the legal responsibility for establishing and maintaining records, and for producing them in a timely fashion, would remain with the testing facility.

41.2 Q: It is possible that an investigation may lead FDA to suspect that a product may have been tampered with inside a vertically integrated operation, for example en route between two facilities. If company systems are set up to establish records as a vertically integrated operation, what would be FDA's expectations if intra-company records were requested?

A: Sections 414(a) and 704(a) of the Act provide access for existing records relating to manufacture, processing, packing, transportation, distribution, receipt, holding, or importation. If FDA requests intra-company records under the Bioterrorism Act, FDA expects a vertically integrated operation to provide access to such existing records as soon as possible, not to exceed 24 hours from the time of receipt of the official request, as required by 21 CFR 1.361.

K. What Records Are Excluded From this Rule? (Section 1.362)

42. General Questions (Reserved)

L. What Are the Consequences of Failing to Establish and Maintain Records or Make Them Available to FDA as Required by this Rule? (Section 1.363)

43. General Questions

FDA has addressed questions we received on this issue in the Final Rule.

M. What Are the Compliance Dates for this Rule? (Section 1.368)

44. General Questions

44.1 Q: Some multinational companies have subsidiaries which may not be food oriented (e.g. trucking lines, barge companies, industrial products). These subsidiaries may be located in many countries around the globe. Should the total number of employees from all the subsidiary companies be included in the total count for the purpose of determining the compliance date for this regulation, or should the count be of those employees within the corporate subsidiary manufacturing (or otherwise associated with) the food article?

44.2 Q: The employee count is limited to the individual company performing covered activities in the United States. 21 CFR 1.368 specifies that all full-time employees in the individual company (i.e., a single legal person) are to be counted, whether or not those employees are engaged in activities related to food subject to this regulation. 21 CFR 1.327(h) provides that foreign persons (except foreign persons who transport food in the United States) are not covered by this regulation.

44.3 Q: A company is foreign-owned and has refineries in 3 other countries. The company's only U.S. location has approximately 60 full-time employees. Worldwide, we have nearly 1000 full-time employees. For the purposes of complying with this regulation, are we considered to have 60 or 1000 employees?

A: The company has 60 employees for the purpose of determining the compliance date for this regulation. 21 CFR 1.327(h) provides that foreign persons (except foreign persons who transport food in the United States) are not covered by this regulation.